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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/051,752	01/16/2002	John D. Puskas	16294-0134 (45044-269130)	*****	
7590 07/07/2005			EXA		
JAMES G. TAUSCHE			LAYNO, CARL HERNANDZ		
5231 POWERS	S FERRY ROAD		<u>.</u>		
ALANTA, GA 30327			ART UNIT	PAPER NUMBER	
,			3762		

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application	on No.	Applicant(s)				
Office Action Commence		10/051,75	10/051,752 PUSKAS, JOHN D.					
Office Action Summary			7/4.	Art Unit				
			8. Layo 105	3762				
Period fo	The MAILING DATE of this communic or Reply	ation appears on the	e cover sheet with the c	orrespondence address				
THE - Exte after - If the - If NC - Failu Any	ORTENED STATUTORY PERIOD FO MAILING DATE OF THIS COMMUNIO MAILING DATE OF THIS COMMUNIO SIX (6) MONTHS from the mailing date of this communical period for reply specified above is less than thirty (30) period for reply is specified above, the maximum stature to reply within the set or extended period for reply within the set or	ATION.  37 CFR 1.136(a). In no evinication. days, a reply within the state tory period will apply and will, by statute, cause the app	ent, however, may a reply be tim utory minimum of thirty (30) day: ill expire SIX (6) MONTHS from lication to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication D (35 U.S.C. § 133).	n.			
Status								
1)🖂	Responsive to communication(s) filed	on <u>04 April 2005</u> .						
2a) <u></u> □	This action is <b>FINAL</b> . 2t	o)⊠ This action is r	on-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposit	ion of Claims		·					
5)⊠ 6)⊠	Claim(s) 1-120 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) 13-24 and 49-120 is/are allowed.  Claim(s) 1,3,4,7-11,25-28 and 37-40 is/are rejected.  Claim(s) 2,5,6,12,29-36 and 41-48 is/are objected to.  Claim(s) are subject to restriction and/or election requirement.							
Applicat	ion Papers							
9)[	The specification is objected to by the	Examiner.						
10)🖂	10)⊠ The drawing(s) filed on <u>04 April 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.							
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11)	Replacement drawing sheet(s) including t The oath or declaration is objected to				d).			
Priority (	under 35 U.S.C. § 119							
a)	Acknowledgment is made of a claim for All b) Some * c) None of:  1. Certified copies of the priority of Some * Copies of the priority of Some * Copies of the certified copies of application from the Internation See the attached detailed Office action	locuments have bee locuments have bee f the priority docum al Bureau (PCT Ru	en received. en received in Applicat ents have been receive le 17.2(a)).	ion No ed in this National Stage				
Attachmer	nt(s)		• •					
1) 🛛 Notic	ce of References Cited (PTO-892)		4) Interview Summary					
2) Notice 3) Information	ce of Draftsperson's Patent Drawing Review (PT mation Disclosure Statement(s) (PTO-1449 or F er No(s)/Mail Date <u>11/26/04,3/4/05</u> .		Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate Patent Application (PTO-152)				

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## **DETAILED ACTION**

1. Acknowledgment is made of applicant's amendment and 3-month extension of time, which were received by the Office on April 4, 2005.

2. Claims 1-120 are pending and active.

# Information Disclosure Statement

3. Acknowledgment is made of applicant's Information Disclosure Statements (PTO-1449) which were received by the Office on November 26, 2004 and on March 4, 2005.

## **Drawings**

4. The corrected formal drawings for Figs.4-13 were received on April 4, 2005. These drawings are approved by the Examiner.

## Claim Objections

5. In view of the applicant's numerous corrections to the claims, the Examiner is withdrawing the objections which were made against claims 51-57, 77, and 78 in the last Office action.

Claim Rejections - 35 USC § 112

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6. In view of applicant's modifications to claim 24, the Examiner is withdrawing the 35 U.S.C 112 rejection, which was made against this claim in the last Office action.

# Claim Rejections - 35 USC § 102

#### Wernicke et al '480

7. Claims 1, 3, 4, and 7-11 are still rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al '480.

Although applicant's arguments with regard to electrodes 12-1 and 12-2 of Wernicke et al '480 were considered valid (i.e. the electrodes residing outside rather than within the esophagus), the Examiner believes the 35 U.S.C 102 (b) rejection is still valid with respect to claims 1, 3, 4, for the case of stimulation electrodes 40-1 and 40-2 which are located within the esophagus 14 of the patient and connected to the vagus nerve 44. See Figs.3 and 4. In regards to claims 3 and 4, electrodes 40-1 and 40-2 operate as bipolar stimulation electrodes (col.9, lines 17-18). For details regarding claims 7-11, applicant's attention is directed to paragraph 7 of the last office action.

# Loos '874

8. Applicant's arguments, see amendment, filed April 4, 2005, with respect to the rejection(s) of claim(s) 37-40, 47, and 48 under Loos '874 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Adams '187.

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#### Adams '187

9. Claims 25-28 and 37-40 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adams '187.

The Adams '187 patent describes a neuro-stimulation device for controlling pain during defibrillation. Various embodiments of this device include a stimulator 34 (Fig. 1) connected via catheters 40,42 to two stimulating electrodes 36,38, for stimulating the vagus nerves 16,12, respectively. Since each electrode stimulates a different area, and no additional electrodes are present, it would be obvious if not inherent to presume the stimulation pulses are unipolar.

In regard to claim 25, stimulating electrodes 36 and 38 are located within the right internal jugular vein 18 and left internal jugular vein 14 proximate the right and left vagus nerves, 16 and 12, respectively (col.4, lines 63 thru col.5, line 5).

In regard to claim 37, another embodiment, shown in Fig.2, describes an external pulse generator 60, having wires 62 and 64 for connecting to two patch electrodes 66 and 68, placed upon a patient's neck for indirectly stimulating nearby vagus nerves 16 and 12, respectively, to relieve pain (col.5, lines 34-43).

## Allowable Subject Matter

- 10. Claims 2, 5, 6, 12, 29-36, and 41-48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 11. Claims 13-24 and 49-120 are allowed.

#### Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (571) 272-4949. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message (carl.layno@uspto.gov) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (571) 272-4955. All faxed communications should be sent to the Office's Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (571) 272-4399.

CARL LAYNO PRIMARY EXAMINER

Carl V. Layro

CHL 7/5/2005